NEW YORK STATE OF OPPORTUNITY. Department of Health

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Guidance for Residential Health Care Facilities Licensed as Class 3A Institutional Dispenser, Limited

The Bureau of Narcotic Enforcement (BNE) is providing this guidance for Residential Health Care Facilities (RHCF) licensed as Class 3A Institutional Dispensers, Limited facilities to assist in their development of policies and procedures for controlled substance drug disposal and destruction. Limited inventory in conjunction with proper disposal and destruction of controlled substances will help mitigate the potential for diversion.

Medications that are prescribed and dispensed to a patient are owned by the patient, known as the "end user" or "ultimate user". Class 3A licensees are given the lawful ability, through licensure, to take temporary custody of a patient's prescribed controlled substances. ***Once a patient is discharged, all medications prescribed to the patient that are in temporary custody of the Class 3A licensee, must be turned over to the patient at the time of discharge, unless they are discontinued by the practitioner who prescribed the medications***. Facilities are not legally allowed to retain possession of a patient's prescribed medications after discharge unless the medication has been discontinued by the prescriber. If patients are not provided with their medications upon discharge, they may not be able to obtain a refill of the controlled substance until the current prescription time period has ended. Upon a patient's death while residing at the facility, however, the licensee may retain possession of the patient's prescribed medications for the purposes of proper disposal.

The first step in reducing potential diversion of controlled substances is to reduce the amount of medication coming into a facility. Facilities should have a full understanding of their patient population and what their patients' medication needs are. To reduce the amount of medication at the facility, controlled substance prescriptions for patients in a hospice or a residential health care facility may be partially filled[1], or prescriptions may be issued for a shorter time period. Facilities are urged to have open dialogue with their medical directors and pharmacy consultants to be able to make informed and accurate decisions regarding the amounts of controlled substances entering the facility. For example, a rehabilitation facility with an average patient admission of 14 days usually does not need a 30-day supply of a medication for their patients. This is especially true for those medications utilized for pain management when, in many instances, the goal is to reduce the patient's use of these medications prior to discharge.

Drug Disposal/Destruction Methods

A. Long Term Care Facilities (LTCF) Pharmacy Collection Receptacles

A 2014 Drug Enforcement Administration (DEA) Rule allows authorized hospitals and retail pharmacies to maintain collection receptacles at Long Term Care Facilities (LTCF). According to the DEA, LTCF means a nursing home, retirement care, mental care or other facility or

[1] Title 10 NYCRR Parts 80.73 & 80.74

institution which provides extended health care to ***resident patients***[2]. Therefore, **not every Class 3A licensee may meet the qualifications required to be recognized by the DEA as a LTCF.**

Both controlled and non-controlled substances may be placed in a collection receptacle. Environmental Protection Agency-listed hazardous pharmaceuticals may be co-mingled with other medications in a DEA-approved collection receptacle, for the purpose of destroying an end user's medications.

A LTCF may only dispose of those controlled substances listed in Schedules II, III, IV, or V that are lawfully possessed by an ultimate user who resides, or has resided, at the LTCF and be placed in the collection receptacle. Schedule I controlled substances, controlled substances that are not lawfully possessed by the resident ultimate user, and other illicit or dangerous substances are not permitted.[3]

At no time may a licensed 3A facility transport a filled drop box liner from the facility for any reason. Only a DEA registered Collector or common carrier may remove the filled liner from the 3A facility.

For more information on using this method of disposal/destruction, refer to Appendix A below.

NYS Drug Take Back Act

Pursuant to Public Health Law §§290-294, the New York State Drug Take Back Act (DTB) mandates that manufacturers establish, fund, and manage a New York State approved drug take back program(s) for the safe collection and disposal of unused covered drugs.

Licensed 3A LTCF's are eligible to participate in this program at little to no cost to the facility. For additional information on how your facility may be able to have a medication drop box installed through the DTB, please go to our web site at: https://www.health.ny.gov/professionals/narcotic/drug_take_back.htm.

B. Mail-Back Envelopes

The DEA allows ***residents*** of a LTCF to utilize a DEA-approved mail-back program[4]. A mail-back program may be conducted by a DEA-authorized collector. LTCFs cannot apply on their own to become a collector or administer a mail-back program. The LTCF may not use the mail-back packages or administer a mail-back program. The LTCF may not use any mail-back envelope program for the purpose of destruction of a licensed 3A's controlled substance inventory.

On behalf of an LTCF resident, an LTCF employee may place the resident's unwanted or unused controlled and non-controlled substances in a mail-back package, seal it, and immediately deposit it into the facility's outgoing mail system[5].

[2] 21 CFR 1300.01(b)
[3] 21 CFR 1317.30, 1317.70, & 1317.75(b)&(c)
[4] 21 CFR 1317.70
[5] K Issue #5; Federal Register Vol 79 No. 174

C. On-site Destruction

As specified in 10 NYCRR Section 80.51, the destruction of controlled substances shall mean that the substances have been ***rendered totally unrecoverable and beyond reclamation***. Single unit doses or partial doses remaining after the administration or attempted administration of a controlled substance may be destroyed on the premises of an institutional dispenser by a pharmacist or nurse provided that:

1. a notation is made in the patient administration record sheet; and
2. the destruction is witnessed by a second pharmacist or nurse or other responsible person designated by the administrator.

It is ultimately the responsibility of the pharmacist or nurse who is destroying the controlled substance, to assure that the method of destruction used renders the controlled substance totally unrecoverable and beyond reclamation.

All federal and state recordkeeping requirements must continue to be met.

Records of all transactions concerning the disposal or destruction of controlled substances, including shipping or tracking information, proof of receipt, and ultimate destruction from the company that owns the container, and receipts must be kept on-file at the 3A facility for a minimum of 5 years.

If a Class 3A facility wishes to utilize this method of storage and disposal as part of their controlled substance diversion mitigation plan, they must request approval from BNE by submitting a written request to bnedestruction@health.ny.gov. This includes a DEA-approved medication drop box and those provided through the NYS Drug Take Back Program.

Additional information and forms on the Drug Take Back Act and the safe disposal of controlled substances, can be found at: https://www.health.ny.gov/professionals/narcotic/.

Onsite Sewering

While still a legal option in some locations, reducing the amount of medications that are sewered should be limited as much as possible and should be a last resort method of destruction when all other options have been exhausted.

Facilities that are within a designated watershed area are not allowed to sewer medications. Please check with your local water district or municipality to determine if your facility is within watershed boundaries.

If sewering is the only available option, it should occur in an area that is not utilized for food preparation, such as a kitchen sink. Direct flushing of the medication should be used without prior alteration of the medication through dissolving, boiling or other methods prior to sewering. Medications should not be mixed together to make a “slurry” prior to sewering. Care should be taken to assure proper Personal Protective Equipment is utilized while sewering medications.

Additional Options

The commercial devices available on the market for drug destruction are continually changing. Some of these devices are only allowed at DEA registered facilities, which 3A licensees are not. It is imperative that a 3A LTCF that wishes to use one of these products, contacts BNE for assistance, before implementing a program that may not meet federal or state regulations.

APPENDIX A
Drug Disposal/Destruction
Long Term Care Facilities (LTCF) Pharmacy Collection Receptacles

The Drug Enforcement Administration (DEA) allows authorized hospitals/clinics and retail pharmacies to maintain collection receptacles at Long Term Care Facilities (LTCF). According to the DEA, LTCF means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to ***resident patients***[6]; therefore, **not every Class 3A licensee meets the qualifications required to be recognized by the DEA as a LTCF.**

Both controlled and non-controlled substances may be placed in the collection receptacle, and Environmental Protection Agency listed hazardous pharmaceuticals may be co-mingled with other medications in a DEA approved collection receptacle.

A LTCF may only dispose of those controlled substances listed in Schedules II, III, IV, or V that are lawfully possessed by an ultimate user who resides, or has resided, at the LTCF may be placed in the collection receptacle. Schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted.[7]

Collection receptacles must meet the following requirements:

- Pharmacies servicing LTCFs can register with the DEA as a collector and place a collection receptacle at an LTCF. LTCFs cannot apply on their own to become a collector.

- An authorized pharmacy, registered with DEA as an authorized collector, may install, manage and maintain a DEA approved collection receptacle at a LTCF.

- Receptacles located in an LTCF must be in a secured area, that is regularly monitored by residential health care facility employees.

- The collection receptacle must be securely fastened to a permanent structure and located in a secured area that is regularly monitored by LTCF supervisory staff.

- Regulations require the installation, removal, transfer, and storage of inner liners be performed either: By or under the supervision of **one employee of the pharmacy and one supervisor-level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the pharmacy; or, by or under the supervision of two employees of the pharmacy.**

- Upon removal, sealed inner liners may be stored at the LTCF for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access.

[6] 21 CFR 1300.01(b)
[7] 21 CFR 1317.30, 1317.70, & 1317.75(b)&(c)

LTCFs that will utilize a DEA approved collection receptacle as their ongoing method of disposal/destruction, must request approval from BNE by submitting the form "**Institutional Dispenser – Limited Medication Drop Box Request"**, DOH-5788, to bnedestruction@health.ny.gov. The request will contain the details of disposal/destruction, which, includes the following:

- Class 3A facility information including:
  - Facility name, BNE license number, address, and telephone number
  - Facility contact person name, and email address
  - Location of installed collection receptacle (including room#, etc.)

- Pharmacy information (for pharmacy that maintains the collection receptacle) including:
  - Pharmacy name, address, and telephone number
  - Pharmacy contact person, and email address
  - Copy of the pharmacy's DEA Collector registration to collect pharmaceutical controlled substances from ultimate users

The LTCF will receive a confirmation email from BNE with an approval for this ongoing method of disposal/destruction. This approval will permit this method of disposal/destruction without prior approval by BNE, and the facility will no longer be required to submit for pre-approval to BNE for a specific destruction date.

The LTCF will be required to:

- Store discontinued/unwanted controlled substances for no longer than 72-hours before placing in the drop box.
- Track all controlled substances that are transferred into the collection receptacle on the Controlled Substance Inventory for Drop Boxes in BNE Licensed Facilities (DOH-5733).
  - DOH-5733 was developed to be used as an "on-going" inventory tracking document. Each time a controlled substance is placed in a DEA/BNE approved receptacle, it is documented on this form at that time.
- Ensure all controlled substances are transferred into the collection receptacle by a licensed healthcare provider who is properly licensed and authorized to administer controlled substances. This should be a nurse and one witness who both sign the appropriate inventory line on the DOH-5733.
- Complete the Request for Approval of Disposal/Destruction of Controlled Substances (DOH-2340) form:
  - Date and time of disposal/destruction is when the inner liner or container was removed to be shipped for destruction;
  - Method of destruction is ***BNE approved collection receptacle;***
  - Location of disposal/destruction is the physical address where the collection receptacle is located and the name of the shipping company taking possession of the inner liner;

        - Personnel conducting disposal/destruction must be a pharmacist from the pharmacy who owns and maintains the collection receptacle and an RN in supervisory capacity from the licensed facility; and
        - A copy of the BNE running inventory form (DOH-5733) must be submitted with the DOH-2340 along with the shipping/delivery receipt showing the liner reached its final destination.
        - BNE will return the DOH-2340 with the approval log number
            - **Synopsis:**
                - Filled liner removed from box by nurse supervisor and a pharmacy/collector employee;
                - Liner is secured in a locked room in a locked cabinet and diversion reduction policies are in-place;
                - Liner is shipped with tracking within 72 hours;
                - DOH-2340, DOH-5733, and completed tracking receipt are emailed to BNE; and
                - BNE will return with DD log number.

- Records of all transactions concerning the disposal/destruction of controlled substances, including shipping/tracking information, DOH-2340, DOH-5733, and receipts must be kept on-file at the 3A facility for 5 years.

- **At no time may a licensed 3A facility transport a filled drop box liner from the facility for any reason. Only a DEA registered Collector or common carrier may remove the filled liner from the 3A facility.**

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Narcotic Enforcement

Institutional Dispenser - Limited Medication Drop Box Request

This form is to be completed and submitted by a Residential Health Care Facility licensed as a **Class 3A Institutional Dispenser – Limited** who wishes to install a DEA approved medication drop box from a DEA registered Collector for purpose of proper destruction of controlled substances.

****TYPE OR PRINT****

CLASS 3A FACILITY

FACILITY OWNER/OPERATOR NAME

D/B/A

MAILING ADDRESS | CITY | STATE | ZIP

BNE CONTROLLED SUBSTANCE LICENSE #

CONTACT NAME | CONTACT TELEPHONE # | CONTACT EMAIL ADDRESS

EXACT PHYSICAL ADDRESS AND LOCATION OF DROP BOX AT 3A FACILITY (i.e., 123 Main St., 2nd floor, Med Room, room 201, south wall)

REQUIRED DOCUMENTATION

Drop Box Photographs	☐	Photos of all exposed sides of the box. Photos of all physical security features. Photos of room entrance and security features of the room as well as where the filled liners will be stored.
Copy of Collector's DEA Registration	☐	Submit copy of DEA Collector registration for Collector who owns and operates the drop box.

AFFIRMATION and SIGNATURE of CLASS 3A LICENSEE ADMINISTRATOR

1. All photographs and documentation submitted are true and accurate representations of the medication drop box, its location, and security.
2. Licensee is knowledgeable concerning all laws and regulations, both State and Federal, regarding the respective licensed activity and shall comply with such requirements.
3. Comply with all requirements of NYS Title 10 CRR-NY 400.4.
4. Licensee affirms that policies and procedures for all aspects of the use of the medication drop box have been developed and provided to all staff responsible for its use. This includes the proper removal and storage of filled liners from the box.
5. Responsible licensee shall promptly report to the Department of Health each incident or alleged incident of theft, loss, or possible diversion of either controlled substances or Official New York State Prescriptions. Such notification shall be reported on the applicable Department of Health form. **Reporting of such incident to other government agencies does not relieve the licensee of this responsibility.**

I affirm that all information contained on this form is true and correct and that I will abide by all laws and regulations pertinent to controlled substances. False statements made herein are punishable as a Class A misdemeanor, pursuant to section 210.45 of the Penal Law.

NAME

TITLE

SIGNATURE | DATE (M/D/YYYY)

Email this completed application and all supporting documentation to: bnelicensing@health.ny.gov (Subject: Drop Box Request)

Mail only if necessary to: New York State Department of Health
Bureau of Narcotic Enforcement
Riverview Center
150 Broadway
Albany, New York 12204

10 CRR-NY 400.4

NY-CRR

OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS OF THE STATE OF NEW YORK

TITLE 10. DEPARTMENT OF HEALTH

CHAPTER V. MEDICAL FACILITIES

SUBCHAPTER A. MEDICAL FACILITIES–MINIMUM STANDARDS

ARTICLE 1. GENERAL

PART 400. ALL FACILITIES–GENERAL REQUIREMENTS

10 CRR-NY 400.4

10 CRR-NY 400.4

400.4 Contracts.

(a) Contracts to perform any services for a medical facility issued an operating certificate or certificate of approval shall:

(1) be in writing, signed by an authorized representative of the facility and the person or agency providing the service and dated;

(2) include each party's responsibilities, functions, objectives, financial arrangements and charges;

(3) require compliance with all pertinent provisions of this Chapter;

(4) include the following language: “Notwithstanding any other provision in this contract, the facility remains responsible for ensuring that any service provided pursuant to this contract complies with all pertinent provisions of Federal, State and local statutes, rules and regulations.”

(b) Medical facilities are hereby authorized, subject to the provisions of this Chapter, to enter into contracts and make arrangements among themselves and among other municipal, State, Federal or privately-owned hospitals, or any medical schools, or other health-related facilities having or utilizing hospital services or facilities, whether or not located in this State or elsewhere, for the:

(1) mutual use, or exchange of medical resources including, but not limited to, real or personal property or employment of personnel;

(2) joint purchases of goods, supplies and services; or

(3) development of medical information, techniques and facilities useful in the progress of the medical art; reduction of medical costs and promotion of a more efficient and effective approach to the delivery of health care services.

10 CRR-NY 400.4